



How to make Organic Plant Breeding mainstream?

WHEN? 9th November 2021

The Hotel. Brussels (www.thehotel.be), Vista room (floor 27)

Boulevard de Waterloo 38, 1000 Brussels, Belgium

[Belgian covid-19 protection rules apply \(proof of vaccination, recovery or test\)](#)

PART 1: Internal event

(accessible to all members of the partner organisers)

09.00 – 09.30	Welcome to the workshop with coffee
09.30 – 11.30	Workshops Topic 1: How to make organic plant breeding mainstream? Topic 2: Organic Varieties – Build together a working definition of organic varieties and pathways for release in the framework of the temporary experiment. Topic 3: Seed Marketing Laws – Set common goals among seed savers and organic breeders for the ongoing reform. Topic 4: Organic Heterogeneous Material – Showcase how the notification could work in practice.
11.30 – 12.30	Joint discussion of the workshop outcomes
12.30 – 13.30	Lunch

PART 2: Public event (hybrid)

Join Zoom Meeting:

<https://zoom.us/j/91400388760?pwd=UjZVTUJBaEdCYjkzZlh5bmlpTE52UT09>

13:30 – 14:00	Welcome coffee
14.00 – 14.10	Welcome and introduction to the event
14.10 – 14.30	Enabling regulatory framework to make organic breeding mainstream: Key message from the morning workshops
14:30 – 16.15	Fishbowl debate with MEPs, DG SANTE, and stakeholders: How to make Organic Plant Breeding mainstream?
16.15 – 16.30	Concluding and closing the event

Organised by the *European Consortium for Organic Plant Breeding (ECO-PB)* in cooperation with *IFOAM Organics Europe, Engagement.Biobreeding, Arche Noah & Biodynamic Federation Demeter International.*



ENGAGEMENT.
BIOBREEDING



**BIODYNAMIC
FEDERATION** demeter

ARCHE NOAH

Background Information:

Regulation (EU) No. 2018/848¹ (the New Organic Regulation), that shall apply from 1 January 2022, defines two different cultivar types which should be promoted in organic agriculture: **Organic Heterogeneous Material (OHM)** and **Organic Varieties suitable for organic production (OV)** (details see Annex I). Under this New Regulation, OHM can be marketed without any DUS and VCU testing but by simple notification and description provided by the breeder. Seed certification is also not mandatory, but seed health issues must comply with Plant Health Regulations. More infos are given in the [delegated acts on OHM](#). To ease the launch of OV, a new temporary experiment is foreseen, that should start in 2022 and last for 7 years. To prepare such temporary experiment, implementing acts are currently under development.

In the scope of the EU Horizon2020 project [LIVESEED](#) status quo analysis on [OHM](#) and [OV](#) were conducted, a [toolbox](#) for describing OHM developed and after several workshops and discussions with CPVO, examination offices, breeders, seed companies, competent authorities and policy makers between 2018 and 2021 and a larger stakeholder and policy maker workshop in cooperation of with Horizon2020 project [INVITE](#) on 4th Feb 2020, [guidelines for adjusted DUS and VCU testing for OV](#) were developed by LIVESEED project.

(See Annex I)

Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material

The Council requested under Article 241 of the Treaty on the Functioning of the European Union (TFEU), through Council Decision (EU) 2019/1905 of 8 November 2019, the European Commission (the 'Commission') to submit a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material ('PRM study'), as well as a proposal, if appropriate in view of the outcomes of the study.

The supporting research study was contracted to ICF (henceforth "[ICF study](#)"). The PRM legislation (12 Directives covering agricultural, vegetable, forest, fruit and ornamental species and vines) establishes rules for the registration of plant varieties and the certification of seed lots and the production and marketing of seed and other plant reproductive material from these varieties. The work carried out by ICF provides an updated review and synthesis of evidence available in literature and insights collected from stakeholders on key aspects of the PRM legislation. It provides an updated PRM legislation problem analysis, identifying current issues, their drivers and implications; explores how recent developments, such as technical developments, new regulations (Official Controls Regulation, Plant Health Regulation) and increasing concerns around biodiversity and food security, impact on PRM issues; and addresses criticisms of previous proposals, by filling gaps in knowledge on the amateur gardener market and addressing Forest Reproductive Material separately. The ICF study finds that the flexibilities afforded to Member States by the Directives have resulted in a range of differences in how variety registration and PRM certification are administered and implemented. The views of stakeholders on the current policy framework and the way forward are mixed.

(See Annex II)

Annex I: Extract related to Organic Heterogeneous Material and Organic Breed Varieties of new REGULATION (EU) 2018/848 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC)

(37) Therefore, plant reproductive material that does not belong to a variety, but rather belongs to a plant grouping within a single botanical taxon with a high level of genetic and phenotypic diversity between individual reproductive units, should be available for use in organic production.

For that reason, operators should be allowed to market plant reproductive material of **organic heterogeneous material** without having to comply with the requirements for registration and without having to comply with the certification categories of pre-basic, basic and certified material or with the requirements for other categories set out in Council Directives 66/401/EEC (1), 66/402/EEC (2), 68/193/EEC (3), 98/56/EC (4), 2002/53/EC (5), 2002/54/EC (6), 2002/55/EC (7), 2002/56/EC (8), 2002/57/EC (9), 2008/72/EC (10) and 2008/90/EC (11), or in acts adopted pursuant to those Directives.

That marketing should take place **following a notification** to the responsible bodies referred to in those Directives and, after the Commission has adopted harmonised requirements for such material, provided that it complies with those requirements.

(38) In order to ensure quality, traceability, compliance with this Regulation and adaptation to technical developments, **the power to adopt certain acts should be delegated to the Commission** in respect of setting out certain rules for the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species.

(39) In order to meet the needs of organic producers, to foster research and to **develop organic varieties suitable for organic production**, taking into account the specific needs and objectives of organic agriculture such as enhanced genetic diversity, disease resistance or tolerance and adaptation to diverse local soil and climate conditions, a **temporary experiment should be organised in accordance with Directives** 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC. That temporary experiment should be for a term of seven years, should involve sufficient quantities of plant reproductive material and should be subject to yearly reporting. It should help to **establish the criteria for the description of the characteristics of that material and to determine the production and marketing conditions** for that material.

Article 3 Definitions

(18) '**organic heterogeneous material**' means a plant grouping within a single botanical taxon of the lowest known rank which:

- (a) presents common phenotypic characteristics;
- (b) is characterised by a high level of genetic and phenotypic diversity between individual reproductive units, so that that plant grouping is represented by the material as a whole, and not by a small number of units;
- (c) is not a variety within the meaning of Article 5(2) of Council Regulation (EC) No 2100/94 (1);
- (d) is not a mixture of varieties; and
- (e) has been produced in accordance with this Regulation;

(19) '**organic variety suitable for organic production**' means a variety as defined in Article 5(2) of Regulation (EC) No 2100/94 which:

- (a) is characterised by a high level of genetic and phenotypical diversity between individual reproductive units; and
- (b) results from organic breeding activities referred to in point 1.8.4 of Part I of Annex II to this Regulation;

Annex II 1.8.4. For the production of **organic varieties suitable for organic production**, the organic breeding activities shall be conducted under organic conditions and shall focus on enhancement of genetic diversity, reliance on natural reproductive ability, as well as agronomic performance, disease resistance and adaptation to diverse local soil and climate conditions.

All multiplication practices except meristem culture shall be carried out under certified organic management.

Article 4 Objectives

Organic production shall pursue the following general objectives:

- (a) contributing to protection of the environment and the climate;

- (b) maintaining the long-term fertility of soils;
- (c) contributing to a high level of biodiversity;
- (d) substantially contributing to a non-toxic environment;
- (e) contributing to high animal welfare standards and, in particular, to meeting the species-specific behavioural needs of animals;
- (f) encouraging short distribution channels and local production in the various areas of the Union;
- (g) encouraging the preservation of rare and native breeds in danger of extinction;
- (h) contributing to the development of the supply of plant genetic material adapted to the specific needs and objectives of organic agriculture;
- (i) contributing to a high level of biodiversity, in particular by using diverse plant genetic material, such as **organic heterogeneous material and organic varieties suitable for organic production**;
- (j) fostering the development of organic plant breeding activities in order to contribute to favourable economic perspectives of the organic sector.

Article 5 General principles

Organic production is a sustainable management system that is based on the following general principles:

Article 6 Specific principles applicable to agricultural activities and aquaculture

As regards agricultural activities and aquaculture, organic production shall, in particular, be based on the following specific principles:

- (d) the maintenance of plant health by preventive measures, in particular the choice of appropriate species, **varieties or heterogeneous material** resistant to pests and diseases, appropriate crop rotations, mechanical and physical methods and protection of the natural enemies of pests;
- (e) the use of seeds and animals with a high degree of genetic diversity, disease resistance and longevity;
- (f) in the choosing of plant varieties, having regard to the particularities of the specific organic production systems, focussing on agronomic performance, disease resistance, adaptation to diverse local soil and climate conditions and respect for the natural crossing barriers;
- (g) the use of organic plant reproductive material, such as plant reproductive material of **organic heterogeneous material and of organic varieties suitable for organic production**;
- (h) the production of organic varieties through **natural reproductive ability** and focussing on **containment within natural crossing barriers**;
- (i) without prejudice to Article 14 of Regulation (EC) No 2100/94 and to the national plant variety rights granted under Member States' national law, the possibility for farmers to use plant reproductive material obtained from their own farms in order to foster genetic resources adapted to the special conditions of organic production;
- (q) avoiding any endangerment of species of conservation interest that might arise from organic production

Article 13 Specific provisions for the marketing of plant reproductive material of organic heterogeneous material

1. Plant reproductive material of **organic heterogeneous material** may be marketed **without complying with the requirements for registration** and without complying with the certification categories of pre-basic, basic and certified material or with the requirements for other categories, which are set out in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC or acts adopted pursuant to those Directives.
2. Plant reproductive material of **organic heterogeneous material** as referred to in paragraph 1 may be marketed following a **notification of the organic heterogeneous material by the supplier to the responsible official bodies** referred to in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC, made by means of a dossier containing:
 - (a) the contact details of the applicant;
 - (b) the species and denomination of the organic heterogeneous material;
 - (c) the description of the main agronomic and phenotypic characteristics that are common to that plant grouping, including breeding methods, any available results from tests on those characteristics, the country of production and the parental material used;
 - (d) a declaration by the applicant concerning the truth of the elements in points (a), (b) and (c); and
 - (e) a representative sample.

That notification shall be sent by registered letter, or by any other means of communication accepted by the official bodies, with confirmation of receipt requested.

Three months after the date shown on the return receipt, provided that no additional information was requested or that no formal refusal for reasons of incompleteness of the dossier or non-compliance as defined in Article 3(57) was communicated to the supplier, the responsible official body shall be deemed to have acknowledged the notification and its content.

After having expressly or implicitly acknowledged the notification, the responsible official body may proceed to the listing of the notified organic heterogeneous material. That listing shall be free of charge to the supplier.

The listing of any organic heterogeneous material shall be communicated to the competent authorities of the other Member States and to the Commission.

Such organic heterogeneous material shall fulfil the requirements laid down in the delegated acts adopted in accordance with paragraph 3.

3. The Commission is empowered to **adopt delegated acts** in accordance with Article 54 supplementing this Regulation by setting out rules governing the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species, as regards:

(a) the description of the organic heterogeneous material, including the relevant breeding and production methods and parental material used;

(b) the minimum quality requirements for seeds lots, including identity, specific purity, germination rates and sanitary quality;

(c) labelling and packaging;

(d) information and samples of production to be kept by the professional operators;

(e) where applicable, maintenance of the organic heterogeneous material.

Article 26 Collection of data concerning the availability on the market of organic and in-conversion plant reproductive material, organic animals and organic aquaculture juveniles

1. Each Member State shall ensure that a regularly updated database is established for the listing of the organic and in-conversion plant reproductive material, excluding seedlings but including seed potatoes, which is available on its territory

2. Member States shall have in place systems that allow operators that market organic or in-conversion plant reproductive material, organic animals or organic aquaculture juveniles, and that are able to supply them in sufficient quantities and within a reasonable period, to make public on a voluntary basis, free of charge, together with their names and contact details, information on the following:

(a) the organic and in-conversion plant reproductive material, such as plant reproductive material of **organic heterogeneous material or of organic varieties suitable for organic production**, excluding seedlings but including seed potatoes, which is available; the quantity in weight of that material; and the period of the year of its availability; such material shall be listed using at least the Latin scientific name;

Annex II Executive Summary of Data gathering and analysis to support a Commission study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material

Introduction: The ICF research study (henceforth "ICF study") set out to collect and analyse data to support a European Commission study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material. The research was undertaken by ICF on behalf of the European Commission's Directorate General responsible for health and food safety (DG SANTE). The legal framework currently comprises 12 Directives, referred to as the Plant Reproductive Material (PRM) legislation. The Directives (covering agricultural, vegetable, forest, fruit and ornamental species and vines) establish rules for the registration of plant varieties in national catalogues and the certification of seed lots and the production and marketing of seed and other plant reproductive material from these varieties.

Context and background: A proposal from the European Commission in 2013 to simplify and update the PRM legislation and harmonise its implementation across the EU was rejected by the European Parliament and subsequently withdrawn by the European Commission. More recently, the Council¹ requested that the European Commission carry out a study on the Union's options to update PRM legislation, and submit a proposal if appropriate in view of the outcomes of the study or otherwise inform the Council of alternative measures.

ICF study objectives: The ICF study builds on earlier works, gathering data with the aim to:

- provide an updated problem definition, identify current issues, their drivers and implications for the PRM legislation;
- deepen the European Commission's understanding of existing and new issues;
- explore how the latest developments, such as technical developments, new regulations (Official Controls Regulation (EU) 2017/625, Plant Health Regulation (EU) 2016/2031) and increasing concerns around biodiversity and food security, impact on the PRM issues; and
- address some of the criticisms raised towards earlier proposals, such as filling gaps in knowledge on marketing to amateur gardeners and address issues in relation to Forest Reproductive Material (FRM).

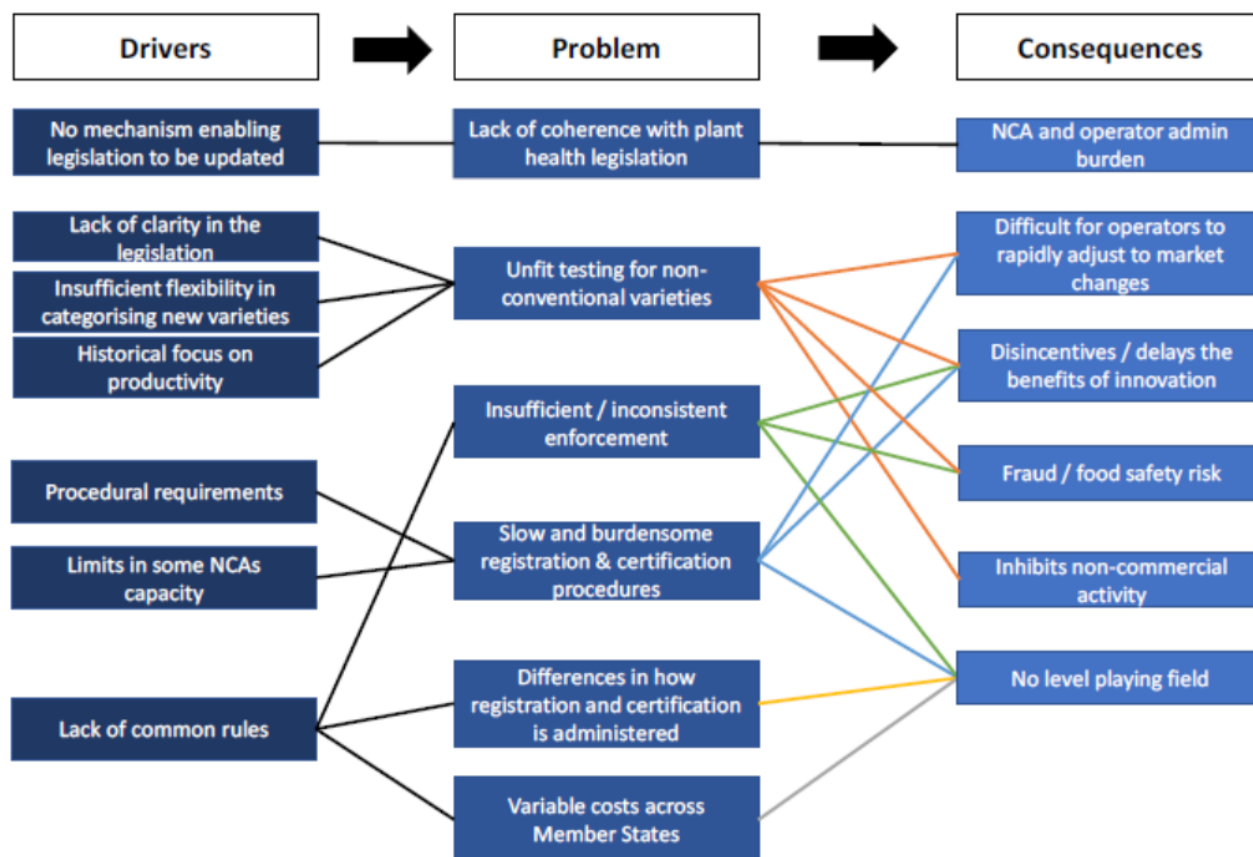
Methodology: A matrix was developed framing the ICF study's overarching approach to evidence collection and analysis and providing links to the research questions. The data collection combined desk-based research and stakeholder consultation through a programme of selected stakeholder interviews, targeted stakeholder surveys, an online workshop, and a validation survey.

Key limitations in the design of the research and methodologies were: the availability of data with reference to the size of the PRM industry; relatively small-scale field research restricted by budget and a limited timetable (six months); and stakeholder self-selection bias.

Key findings and conclusions

Problems with the existing PRM legislation: Figure 1 provides a simplified overview of the problem analysis, indicating problems identified, their drivers and consequences.

Figure 1. Simplified problem tree analysis



The six key problems identified were:

1. There are differences in how registration is administered across Member States. This is a problem, for example, when VCU tests are carried out on agricultural species, in terms of how VCU criteria are interpreted, weighted, and how test results are calculated and assessed, which undermines the EU level playing field.
2. There are differences in how Member States calculate fees (and share costs) for variety registration and PRM certification, which undermines the EU level playing field and can have a potential greater impact on SMEs and non-profit organisations with commercial activities. The lack of common rules in the Directives on how costs are calculated or shared between operators and NCAs results in operators facing different costs for registration and certification in different Member States. Mutual recognition of registered varieties across the EU (through the common catalogues) mitigates the impact of different registration processes to some extent.
3. Testing for conservation and amateur varieties and varieties intended for organic production does not appropriately reflect the needs of these varieties, impacting the ability of operators to register new varieties. There is insufficient flexibility in legislative requirements (testing criteria) for these varieties, whilst there is also a lack of clarity in the language and terminology used in the legislation. The use and application of derogations is variable across Member States.
4. The registration process requires time and can be burdensome. However, it is a key safeguard ensuring the quality of PRM on the market. Whilst the legislation permits the transfer of aspects of the certification procedures, certain conditions, to industry through a system of certification under official supervision, that option is not currently feasible for registration purposes (i.e. DUS and VCU testing). Differences in NCA capacity and performance can result in differences in the time required for registration.
5. There is a lack of coherence between the PRM marketing legislation and the Plant Health Regulation on the issue of regulated non-quarantine pests (RNQPs), resulting in uncertainty for NCAs in terms of which list to consult.

6. Terminology used to describe aspects of the control requirements in the PRM legislation is ambiguous and is interpreted differently across Member States resulting in inconsistent and potentially insufficient control and enforcement. Although for some Member States the flexibility afforded by the Directives is desirable.

Non-harmonised implementation of the legislation:

Key differences identified between Member States related to:

- the registration systems of Member States (including the effectiveness of the system, speed and ease of the process, appropriate testing stations etc.). These can impact the decisions made by industry on where to register a variety. The 'typical' length of the registration process varies between 1 to 5 years, depending on the species and Member State.
- discrepancies in relation to the characteristics used to assess VCU tests. A number of Member States use single key characteristics (especially in species where the yield increase is not very high) to assess VCU tests. Some use an index weighting approach across multiple criteria, while others use a mix of both approaches. In almost all Member States decisions can also be made on the basis of overriding criteria, most frequently linked to high quality varieties or varieties with special characteristics such as high resistance to pests. In most Member States there is no formal inclusion of sustainability criteria in VCU tests.
- Member States' approaches to registering organic varieties, with only a small number having a separate system.
- the extent of variety reference collections (ranging from less than 5,000 to over 50,000 varieties) and how they are maintained: most Member States use living variety collections and databases with characteristics and descriptions, although the relative popularity of the methods differs by species.
- the cost of registration and technical fees charged for testing. Although cost was not identified as a deciding factor in choosing where to register a variety, it can be a barrier to SMEs and non-profit organisations marketing PRM. Member States also take different approaches to cost recovery: less than half have some system of cost reduction in place for applicants, although in some Member States this is only for conservation and amateur varieties.
- the frequency of reporting new registered varieties to the Common Catalogues with timeframes ranging from multiple times per month to once per year.
- divergent Member States' approaches to control and enforcement.

Synergies with the Plant Health Regulation: There is an overlap between the PRM Directives and the Plant Health Regulation on the issue of regulated non-quarantine pests (RNQPs). Duplication in the listing of RNQPs (albeit with some differences) has resulted in confusion on which list should be consulted by Member States authorities. This has meant additional effort to check both lists and to ensure appropriate application of the legislation. Some Member States argued in favour of a single document listing RNQPs with a preference for that to be the PRM Directives which allows Member States to include the RNQP list in the national regulation. However, some of the pests currently in the PRM Directives were not recommended for listing as RNQPs in the Plant Health Regulation and hence such differences are likely to remain.

Synergies with the Official Controls Regulation: The PRM legislation does not fall under the Official Controls Regulation (OCR). Harmonising rules on control across Member States was considered beneficial by the majority of NCAs. Opinion on whether to include the PRM legislation in the OCR was mixed. Arguments in favour of inclusion focussed on the efficiency of implementation (with inclusion in the OCR clarifying and streamlining responsibilities within Member State authorities), and harmonisation in the costs of compliance across Member States. Arguments against valued the flexibility currently afforded by the PRM Directives and highlighted additional complexity and additional burden for NCAs from inclusion of the PRM legislation under the OCR.

Technical developments in the breeding sector: A growing number of New Genomic Techniques (NGT) have emerged, making use of plant genetic information in the breeding process to alter the genome of organisms. Of relevance to the PRM legislation is the extent to which the varieties and PRM resulting from NGTs are accessible to farmers and are subject to the existing registration and certification requirements. There is a need for transparency in how varieties obtained through NGTs are registered and certified, if allowed in the EU.

Digitalisation: In an increasingly digitalised world, there is potential for digital solutions, such as blockchain technology or the use of Digital Object Identifiers (DOI), to improve traceability, and offer greater assurance on the identity, quality and health of seeds, although stakeholders noted that transparency in the sector is improving. Digital illiteracy, poor connectivity and costs remain key barriers in the adoption of such technologies, with a small number of stakeholders also raising concerns over safety, ownership and confidentiality of the information.

The amateur gardener market: The ICF study engaged maintainers of varieties intended for amateur gardeners (hobby gardeners). The key findings were:

- There is mixed evidence regarding the number of varieties available to amateur gardeners, although the ICF study stakeholder survey points to an increase over the past 10 years. This is likely to vary depending on the species.
- Most amateur gardeners are primarily involved in gardening to grow edible produce for themselves and their families, for enjoyment and to enhance their aesthetic setting. A large number of gardeners also considered produce they grow important in meeting their dietary needs. As a result, their preferences when purchasing PRM differ from those of commercial producers. Amateur gardeners ranked the health and quality of varieties, and the availability of varieties with cultural or historical significance (such as heirloom or conservation varieties) as the most important factors.
- The majority of amateur gardeners suggested that the health, quality and identity of purchased seeds have met their expectations. Some differences existed between Member States. Amongst those who reported encountering problems most referred to plants that did not correspond to the characteristics described on the seed packaging and to bad quality seeds (i.e. low rates of germination). While the majority of amateur gardeners were happy with the diversity of choice available to them, many would like to see greater choice of traditional, regional/local and organic varieties.
- A lighter registration regime for varieties intended for amateur gardeners could improve both the availability and genetic diversity of the PRM available to amateur gardeners. However, adopting a lighter regulatory regime for varieties aimed exclusively at amateur gardeners may increase risks to the assurance of PRM identity, quality and health.

Amateur and conservation varieties and preservation seed mixtures: The PRM Directives allow derogations for amateur varieties, conservation varieties and preservation seed mixtures providing lighter market access. Despite this, there is limited use of amateur varieties, conservation varieties and preservation seed mixtures. Key reasons identified were:

- Low market demand, relatively high production costs and low profitability compared to commercial varieties mean the market is unattractive for commercial companies.
- Players involved in the production of native seeds, which are often used in preservation seed mixtures, are typically small-scale, not-for-profit producers. Extent to which NCAs and public bodies in Member States encourage registration of conservation varieties and recognise their role in supporting biodiversity conservation.

There were mixed views on whether legal limits on production volumes are in fact limiting the size of the market. However, an expert advisor (member of the researched team) warned that removing the production limits could put conservation and amateur varieties in direct competition with commercial varieties, placing an advantage on the former in terms of varietal registration.

Requirements and costs for registering conservation and amateur varieties differ across Member States, although registration fees are generally lower than for conventional varieties³ and in some cases are zero. Stakeholder views were mixed regarding the limitations imposed by the Directives on the production, maintenance and marketing of conservation varieties to their region of origin with some calling for a more flexible approach. Overall, stakeholders favoured a species-by-species approach to assess the risks related to any relaxation of region of origin rules, rather than a one-size-fits-all approach.

Forest reproductive material: The key problems related to the identity and traceability of FRM, and user information needs. Research institutes and academia constituted the majority of the respondents indicating a problem with the conservation of genetic diversity.

Issues around FRM **identity and traceability** were caused by the existing levels of control in the production and marketing of FRM. Contributing drivers were:

- Insufficient resources in NCAs.
- Insufficient guidance on how to identify and record the identity of FRM in relevant documentation.
- Insufficient information on FRM and its identity is collected and/or shared when a product is marketed.
- Information on basic material could be improved.
- Documentation on FRM identity (such as supplier's documents) is not uniformly completed across Member States.

Suggestions to support increased accountability and improve practices along the production chain and marketing of FRM included: making Master Certificate codes/reference numbers and/or Master Certificates public at a national level; the use of genetic markers; and a voluntary approach to keeping and sharing records of FRM from basic material.

Relating to the problem of the conservation of genetic identity in FRM, the following main drivers were identified:

- Harvesting and distribution of seed stands.
- Intensive use of single seed source.
- Limited transfer of FRM across borders.
- In addition, around half of all stakeholders identified access to state-owned FRM and access to certain types of seeds as drivers.

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	<i>Revision of the plant and forest reproductive material legislation</i>
LEAD DG (RESPONSIBLE UNIT)	DG SANTE.G1 – Plant Health
LIKELY TYPE OF INITIATIVE	<i>Legislative</i>
INDICATIVE PLANNING	<i>Q4 2022</i>
ADDITIONAL INFORMATION	<i>Future of EU rules on plant and forest reproductive material</i>

A. Context, Problem definition and Subsidiarity Check

Context
<p>Plant reproductive material (PRM) are plants and all parts of plants capable of, and intended for, producing entire plants for any purpose such as food, industrial uses, forestry or decoration (ornament). It may include seeds, young plants, tubers or plant cuttings. PRM constitutes the very beginning of the agri-food production chain to ensure the availability of diverse, healthy and high-quality food. The EU legislation on PRM is based on two pillars: certification of PRM to be marketed and registration of the varieties of that PRM. A plant variety represents a group of plants with a common set of characteristics (e.g. a plant species can include from a few to hundreds of different plant varieties). In order to be placed on the EU market, new plant varieties have to be tested to show that they are distinct from other varieties, uniform and stable. Moreover, the PRM legislation ensures the identity, quality and health of the marketed PRM for the user. The breeding of new plant varieties contributes to the diversity of PRM that will in turn contribute to the diversity of food available on the market. For example, breeding can result in plant varieties producing strawberries in early spring, or in late summer. Likewise, plant varieties can respond to consumer preferences e.g. big versus small strawberries. More importantly, new plant varieties and plant breeding play an indispensable role in creating plants capable to face the current challenges such as extreme weather events (e.g. withstand heavy winds due to a deeper rooting system), extended drought periods and new plant pests. Furthermore, plant varieties may contribute to a more sustainable farming system by decreasing the use of plant protection products.</p> <p>Forest reproductive material (FRM), is a particular type of PRM, namely forest seeds and plants, which constitute the starting point for the creation of new forests and the reforestation of existing forests. Global warming has a negative and increasing impact on Europe's forests by shifting biogeographical regions northwards and uphill. FRM that used to be optimal for a given region may no longer be fit for that region because of the changing climatic conditions. The FRM legislation helps to identify FRM and specifies the requirements, such as origin, health and resistance, wood quality, outstanding characters, to be met by trees that will be used for the production of the different types of FRM. The legislation on FRM has been developed as a very particular part of the PRM legislation, with its own basic concepts and approaches that significantly differ from the other PRM sectors. Therefore, and when so needed, special reference to FRM will be made.</p> <p>The current legislation on the production and marketing of seed and other PRM is composed of 11 Directives, specific for each type of crop (e.g. cereals, fodder plant, oil and fibre plants, beet, seed potatoes, vegetables, ornamentals, fruit plants, vine, FRM) and one Directive establishing the common catalogues of varieties of agricultural species. The aim of these marketing Directives is to lay down requirements for the production and marketing of the different types of PRM and the necessary certification/inspection methods for issuing labels and certificates for the final packages of PRM, so that the users have the necessary information and guarantees.</p> <p>In 2013, the Commission started a review process of the legislation, adopting a proposal for a Regulation on the production and marketing of plant reproductive material including FRM ('2013 PRM proposal'). In 2015 the proposal was subsequently withdrawn after rejection by the European Parliament in 2014. In May 2021, the</p>

Commission presented a study on possible options to update the existing legislation on the production and marketing of plant reproductive material, which had been requested by the Council¹. The study concluded that the Commission should continue preparatory work to review the existing legislation

Problem the initiative aims to tackle

The current legislation has proven its success in guaranteeing the identity, performance, quality and health of all PRM. Moreover, it has contributed to fostering an internationally competitive PRM industry. Therefore, the core principles of the existing legislation remain valuable for commercial PRM production but there is room for improvement.

Firstly, the content of the 12 Directives is not aligned which causes a lack of coherence, such as different definitions for the term 'marketing' or 'operator'. It leads to inconsistencies in their interpretation for users and competent authorities. This has led to an uneven implementation and application, which creates a non-level playing field and different (market) conditions for operators in the Member States, and thus hinders the smooth operation of the internal market (problem 1). Secondly, the legislation further includes a set of complex and rigid procedures, which result in a high administrative burden in particular for competent authorities and operators. The different and detailed technical requirements included in the 12 Directives create a cumbersome decision-making process for adapting the legislation in case of scientific developments (problem 2).

Problem 1: Divergent implementation practices and non-level playing field

The non-aligned or missing definitions in the Directives have caused different approaches for addressing the same issues, such as adding new species to the scope of the Directives. In some Directives, the procedure for adding or deleting species covered requires an act adopted by the Commission, while in others it requires an act to be adopted by European Parliament and Council. Some Directives do not have specific instruments for protecting conservation varieties² (i.e. the Directives for fruit and vine), while such instruments exist for agricultural and vegetable Directives. The approach for authorising non-EU-countries to export PRM to the EU is also inconsistent across the Directives, which in certain cases requires an approval by the European Parliament and the Council, while in others simply a Commission implementing act.

The definitions of 'marketing' and 'operator' are ambiguous in certain Directives or missing in others, and leave it open if the activities of seed conservation networks³ are covered by the PRM legislation or not, and -if so- to what extent. Furthermore, amateur gardeners have different uses and motivations compared to professional users and this raises the question if PRM marketed to amateur gardeners should be subject to the same rules as PRM marketed to professional users.

Heavy procedures for testing and certification create burdens for operators as some of the certification activities can only be carried out officially. This approach is not aligned with more recent developments in the policy governing official controls and other official activities carried out by Competent Authorities, which recognise the role of activities carried out by operators under official supervision in reducing administrative burdens and ensure an efficient use of public resources.

Member States have used the possibility offered by the legislation to deviate or exempt from the applicable rules in different ways, which causes problems for products marketed in different Member States.

There is no harmonised and risk-based framework for official controls, which limits the ability for Competent Authorities to enforce risk-based measures to ensure the identity, health and quality of PRM. This results in differences of control and enforcement across Member States.

Problem 2: Legislation prevents innovation and use of new technologies and adaptation to policy developments

The creation of synergies with the Green Deal and its related strategies (Farm to Fork Strategy, the Biodiversity Strategy, the EU Adaptation Strategy on adapting to, and mitigating, the impact of climate change, the new EU Forest Strategy on healthy and resilient forests and the European Digital Strategy), is often hindered because complex and rigid procedures and requirements in the current PRM legislation do not pursue always the same objectives as these strategies. Following the withdrawal of the 2013 PRM proposal, the PRM legislation, which

¹ Commission Staff Working Document SWD(2021)90 Study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material

² Conservation varieties are landraces and varieties of agricultural and vegetable species traditionally grown in certain regions.

³ 'Seed conservation networks' are operators exchanging and marketing PRM in limited amounts with the main non-profit purpose of conserving plant and forest genetic resources.

dates back to the 1960s, is in any case not aligned with more recently adopted legislation and the aforementioned strategies.

The lack of clear rules on testing for Value of Cultivation & Use (VCU) and the absence of sustainability criteria (e.g. reduced use of plant protection products and adaptation to changing climatic conditions) in the EU legislation have caused considerable differences between Member States in relation to the sustainability characteristics of new varieties. This in turn has impeded an adequate response to the demand for more sustainable agri-food production.

Currently, the availability of organic seed and of organic varieties suitable for organic cultivation is insufficient. It is important to set appropriate conditions for their development to foster the goal of the Farm to Fork Strategy of reaching 25% of agricultural land under organic farming by 2030. As organic varieties have to be characterised by a high level of genetic and phenotypical diversity between individual reproductive units, the current VCU tests and testing protocols for the distinctness, uniformity and stability (DUS) of varieties are not yet adapted to the needs of organic varieties suitable for organic cultivation. Due to the lack of organic varieties suitable for organic cultivation and a derogation in the organic legislation allowing the use of untreated non-organic PRM, this PRM is still used to varying extents in different Member States for organic production.

The legislation hinders the introduction of new/adapted rules on innovative production processes, which creates barriers for the market access of PRM products obtained through scientific and technical progress. Moreover, the current rules limit or do not place enough emphasis on the use of scientific and technical developments, such as certain biomolecular techniques.

Member States can choose to either apply or not lighter conditions for the registration of amateur and conservation varieties. When the requirements and costs for registering conservation and amateur varieties are identical to those of new varieties, there may be little incentive for seed conservation networks and other operators active in this domain to register conservation and amateur varieties⁴, negatively affecting the diversity of seeds and PRM that contribute to biodiversity and resulting in lack of alignment with recent Commission Strategies. In addition, the current legislation restricts increasing consumer demands for these traditional and local varieties due to production limits imposed by the existing legislation.

Basis for EU intervention (legal basis and subsidiarity check)

The PRM legislative framework is based on **Article 43** of the Treaty on the Functioning of the European Union (TFEU) implementing the Common Agricultural Policy (CAP). The Lisbon Treaty qualifies agriculture as shared competence between the EU and its Member States. All fields of agricultural activity as well as ancillary activities upstream and downstream have been regulated to a very large extent at EU level. **Article 114** provides the legal basis for the establishment and functioning of the internal market and the approximation of provisions laid down by the law, regulation or administrative actions. **Article 191** states as the objectives of EU environment policy the preservation of the environment, the prudent and rational use of natural resources as well as promoting measures at international level to deal with environmental problems.

The introduction of the EU Directives on the marketing of PRM starting in the 1960s has been a major contributor to the creation of an internal market. The evaluation carried out in 2007 – 2008 confirmed that the EU rules on marketing of PRM have had a generally positive impact on free movement, availability and quality of PRM on the EU market and have thus facilitated trade within the EU, despite the still prevalent problems. If there had been no action at EU level, 27 systems instead of one would be in place today. This would put even more serious obstacles to the movement of PRM on the internal market and increase the financial burden associated with the necessary controls on the health and quality of PRM. Therefore, a common EU framework should be retained, and where possible strengthened, as it is considered to be the most appropriate approach.

B. Objectives and Policy options

⁴ Amateur varieties are varieties with no intrinsic value for commercial production but developed for growing under particular conditions (i.e. they are mostly used by amateur gardeners).

The general objectives are to remove any obstacle or barrier in the internal market in order to ensure a level playing field for the marketing of PRM. For all types of users and consumers, a wide diversity of choice of PRM should be ensured. The revision also supports innovation and competitiveness of the EU PRM industry. Finally, it should contribute to the objectives of the Green Deal and its related Farm to Fork, Biodiversity, EU Climate Adaptation, European Digital and New EU Forest Strategies. In particular, it should support adaptation to, and mitigation of, the impact of climate change, and contribute to food security, sustainable production and biodiversity protection.

The specific objectives are to:

- Increase coherence of the legislation through simplified and harmonised basic rules on fundamental principles (e.g. scope of application, definitions of ‘marketing’ and ‘operator’);
- Eliminate fragmentation of requirements that results in adjustment of costs for operators;
- Increase the efficiency/effectiveness of the PRM sector through the establishment of simplified, more flexible and proportionate procedures;
- Clarify rules for seed conservation networks and PRM marketed to amateur gardeners;
- Establish appropriate conditions for the development of organic varieties suitable for the organic production;
- Empower Competent Authorities to allocate control resources through a harmonised and risk-based framework for official controls;
- Support the conservation and sustainable use of plant and forest genetic resources to promote the development of diverse farming systems, defend biodiversity, adapt to, and mitigate, the impact of climate change and contribute to food security;
- Introduce lighter requirements for conservation varieties for all PRM sectors and, where appropriate, for amateur varieties;
- Support innovation and the development of digital technologies and bio-molecular techniques in the PRM sector.

To address the identified problems, and achieve the above objectives, several policy options will be considered in the impact assessment. Those options will be developed on the basis of the following options.

Policy choices

Baseline: Do nothing.

No changes to the current legislation; focus on implementing the legislation in a way, which takes into account, to the extent possible, the objectives of the Green Deal and the Farm to Fork Strategy.

Option 1: Alignment of definitions and structure of the legislation

This option would keep all 12 marketing Directives. It would include alignment and simplification of the structure of the legislation and decision-making procedures and introduce flexibility for operators. It would also introduce measures in support of sustainability. It would focus on the needs of the professional sector. It would establish a lighter registration system for PRM marketed by seed conservation networks and PRM marketed to amateur gardeners but PRM would still need to comply with the requirements of the marketing legislation as regards identity, health and quality of the material. Exchange of PRM between farmers would remain in the scope of the PRM other than FRM legislation, meaning that it would be considered as ‘marketing’.

The amendments would concern:

- Aligning the structure, definitions and decision-making procedures between the Directives;
- Adding definitions on terms such as operator/marketing where missing and/or streamline definitions across Directives;
- Establishing and aligning instruments for protecting conservation varieties in all Directives and, where appropriate, for amateur varieties;
- Removing duplications in inspections, inconsistent rules applicable to the same material and ensuring coherence with the plant health, GMO and organic legislation;
- Relying on tertiary legislation to set requirements and to adapt these requirements to technical and scientific developments;
- Increasing the number of tasks that operators may carry out under supervision of the competent authorities such as the tests carried out for registration and certification;

- Including guidance on how to record the characteristics determining the identity of FRM in relevant documentation;
- Supporting the Green Deal objectives through measures addressing climate change mitigation and adaptation, the conservation and sustainable use of plant and forest genetic resources and the protection of biodiversity;
- Supporting the Farm to Fork Strategy by facilitating the marketing of varieties adapted to the needs of organic agriculture through e.g. adapted DUS and VCU tests and contributing to reaching the organic objective of the Farm to Fork Strategy;
- Amending existing official control rules and adding new rules, catering for the specific needs of the respective sector.

Option 2: Alignment of definitions and structure of the legislation while matching needs of professional sector, seed conservation networks and users

This option would include the general amendments as described under option 1 and additionally would exempt seed conservation networks and marketing to amateur gardeners from the scope of application of the legislation. Exempting the marketing of limited amounts of PRM, in particular by seed conservation networks for non-profit purposes, would incentivise PRM diversity, and boost and promote the marketing of more local and traditional products. It would be analysed if, and how, reducing the overall number of Directives is advantageous and/or constitutes a legal simplification. The FRM legislation would still be kept as a separate legal instrument because the production and certification process of FRM, as well as its basic concepts, are distinct from the one of the other sectors.

The further amendments would concern:

- Scope of application of the PRM other than FRM legislation: clarifying exemptions and in particular create a specific EU framework for the exchange in kind between farmers of PRM and services restricting this activity e.g. to farmers belonging to an association/network; limiting the scope of application of the PRM other than FRM legislation to the professional sector, excluding seed conservation networks and amateur gardeners from the scope of the legislation. No EU rules or national rules should regulate seed conservation networks and the amateur market. Those sectors could be self-regulated;
- Introducing modern and flexible processes adapted to new technologies to enhance the efficiency of the certification/inspection and variety registration systems, and label security, traceability and integrity of PRM;
- Introducing mandatory sustainability criteria into variety testing;
- Including or excluding the PRM legislation in the scope of the Official Controls Regulation;
- Keeping the scope of the FRM legislation or extending the scope to certain clearly defined non-forestry purposes (agroforestry and biodiversity purposes, biomass and energy generation).

Option 3: Full harmonisation of the legislation

This option would create a full harmonisation by proposing one single policy instrument with specific chapters for the different crop groups. The policy instrument on FRM would still be kept separate. The professional sector, seed conservation networks and marketing to amateur gardeners would be covered by the scope of the legislation. Exchange of PRM between farmers would remain in the scope of the PRM other than FRM legislation, meaning that it would be considered as 'marketing'. This option would focus on PRM quality and high guarantees for users and would improve conditions for its free circulation within the internal market. Derogations and exemptions from the requirements of the legislation would be kept to a strict minimum, by restricting the possibility for Member States to establish less or more stringent national requirements for marketing in comparison to the respective EU requirements. PRM would be included in the scope of the Official Controls Regulation.

In addition to the measures proposed under the bullet points under option 1, the amendments would concern:

- Scope/applicability of the PRM other than FRM legislation to the marketing of varieties of PRM to professional and non-professional end users;
- Applicability of the FRM legislation exclusively to FRM marketed for forestry purposes;
- Including PRM into the scope of the Official Controls Regulation.

C. Preliminary Assessment of Expected Impacts

<p>Likely economic impacts</p> <p>Offering more flexibility to operators would increase the responsiveness and adaptability of companies in bringing PRM to the market. It would continue contributing to food and nutritional security for EU citizens and ensure the availability of sufficient and diverse FRM for afforestation and reforestation. This would have an overall positive economic impact on operators and consumers. The sector's international competitiveness would also be improved. The possibility to carry out variety testing and field inspections and to produce PRM under official supervision would increase the efficiency of the sector and, in addition, would decrease administrative burdens and costs for Competent Authorities. Many SMEs and smaller companies with limited human resources, however, would continue to depend on the expertise and human resources of the Competent Authorities for variety registration and certification and this may limit the savings made by Competent Authorities. Lighter and less costly registration requirements for certain variety types (e.g. conservation varieties) would create more equal conditions for operators across the EU Member States and improve income of small companies producing for niche markets, reducing also costs for other operators. More responsiveness of the legislation to new technical developments in the PRM sector by simplifying procedures to adapt the legislation would support innovation and research, and therefore also competitiveness, in an already research-intensive sector, with positive economic impacts on all types of operators in the sector. A more harmonised implementation of the Directives through, for example, clearer definitions of exemptions to the scope of application and a harmonised and risk-based framework for controls, would help achieve more even conditions and create similar opportunities for producers in different Member States.</p>
<p>Likely social impacts</p> <p>The PRM sector, in particular the breeding industry and FRM sector are highly innovative involving a highly skilled workforce and state of the art facilities. A strong, sustainable and internationally competitive breeding industry and FRM sector would support the creation and maintenance of skilled employment in rural and remote areas. European cultural heritage finds its expression also in landscape and agricultural diversity, and diversity of forests. Facilitated procedures for the registration of conservation and amateur varieties and FRM naturally adapted to local and regional conditions would contribute to the protection and continued viability of this heritage.</p>
<p>Likely environmental impacts</p> <p>Supporting PRM, which contributes to species diversity, genetic diversity within tree species (FRM) and within-field genetic diversity (mixtures of varieties, heterogeneous material, organic varieties) would help lowering the environmental impact of agriculture and forestry. Genetic diversity of a crop in the field could ensure a greater likelihood that, for example, not all plants in the field will be lost in extreme weather events (e.g. better resistance to drought of individual plants) or when the plants are attacked by damaging plant pests. Likewise, genetic diversity within a single tree species is of utmost importance to avoid that entire forests can be wiped out by, for example, bark beetle infestations. Lighter rules for the registration of conservation varieties and creating conditions for amateur gardeners to have a wide choice of old and new varieties, would establish conditions for the conservation of genetic diversity in fields and in gardens, which will therefore remain available for future breeding efforts.</p> <p>In the testing of new varieties during the registration process, sustainability criteria would address resistance to threats from plant pests and from adverse weather conditions. Introducing mandatory sustainability criteria into variety testing would support the development of more climate-proof varieties, which are e.g. resilient in the face of extreme weather events and/or are tolerant or resistant to plant pests. This would contribute to enhancing food security. Establishing a specific system for the registration of organic varieties would support the growth of organic agriculture and help avoiding the use of plant protection products and other external inputs, thereby supporting two core aims of the Farm to Fork Strategy. It is the combination of actions and characteristics at species and variety level that would support adaptation in land ecosystem management and allow adapting to, and mitigating, the impact of climate change.</p> <p>Improved FRM legislation combined with sustainable forest management would result in healthy and resilient forests that would contribute to adaptation to, and mitigation of, the impact of climate change, and would better protect biodiversity.</p>
<p>Likely impacts on fundamental rights</p> <p>None</p>
<p>Likely impacts on simplification and/or administrative burden</p> <p>Legal simplification would improve the coherence of the legislation and lead to a better implementation, with less burdens for operators active in more than one Member State or in more than one sector.</p> <p>Increased flexibility would be achieved by widening the possibility for operators to carry out tasks (inspection/certification, elements of variety testing, FRM production) under the supervision of the Competent Authorities. Companies could more efficiently plan their operations in line with their needs and capacities and could make effective use of in-house expertise. Reducing the complexity of procedures and cumbersome</p>

decision-making processes, increased flexibility and uptake of new technologies (digitalisation, bio-molecular techniques) would reduce administrative burdens for Competent Authorities and increase efficiency of the system, in particular for SMEs developing innovative breeding and PRM production methods.

A harmonised and modern system for risk-based official controls, supported by the deployment of digital technologies and training, would lead to efficiency gains. Especially the introduction of risk-based controls would allow operators, who have a proven track record of reliable production, to make efficiency gains, while Competent Authorities can focus control efforts where they are most needed.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment will be carried out to support the preparation of this initiative.

Evidence base and data collection

The impact assessment will be based on the following documents:

- The [evaluation](#) carried out in 2007-8;
- The [impact assessment](#) of 2013;
- The [PRM study](#) requested by the Council;
- The [contractor's report](#) supporting the study.

An additional study will be commissioned to support the impact assessment process during the second half of 2021. Findings from the PRM study and the aforementioned additional study will be used to source evidence to assess the impacts of the proposed options, developed on the basis of the options presented above (as well as to further refine such options). In particular, those studies will provide data on expected economic, social, environmental and administrative impacts.

Consultation of citizens and stakeholders

Interested parties will be consulted through a mix of open and targeted consultations. Consultations will be carried out to engage all relevant stakeholders and seek their opinion on the main policy approaches and how they would be affected by them.

The consultation activities will involve all the main stakeholder groups, including Member States' Competent Authorities, PRM industry representatives, farmers' organisations and other interested partners, such as international organisations active in this domain and civil society representatives. An SME test will be carried out.

From November 2021 to February 2022, a public consultation is scheduled to take place via an online questionnaire. This consultation will be available in all official EU languages and will be accessible via the Commission's central [public consultations page](#) ('Have Your Say').

Will an Implementation plan be established?

An implementation plan could be established based on the impact assessment performed. Where necessary, guidance documents could be developed.